ALPHATEC SPINE INC. K063668

510(k) SUMMARY

ROC™ Lumbar System
510(k) SUMMARY
March 2007

MAY 18 2007

Company: Alphatec Spine, Inc.
2051 Palomar Airport Road#100
Carlsbad, CA 92011 USA
Telephone: (760) 431-9286
Fax: (760) 431-9132

Contact Person: Paula Morgan, Director of Regulatory Affairs

Trade/Proprietary Name: ROC™ Lumbar System

Common Name: Pedicle Screw Spinal System

Classification Name: Pedicle Screw Spinal System (888.3070)

Product Description:

The ROC™ Lumbar System is a posterior system used to attain vertebral fusion and/or stabilization in L3-S1. The subject components of this submission are rods, rod connectors, and a rod connector adjustor.

The rods are manufactured from Ti 6Al-4V ELI conforming to ASTM F136 or CP Titanium conforming to ASTM F67. The offset rod connectors are made of Ti 6Al-4V ELI conforming to ASTM F136 and come in a two sizes to accommodate the patient's anatomy and levels of fusion. The connectors will be used as part of the ROC™ Lumbar System

Indications for Use:

It is intended that this device, in any system configuration, be removed after the development of solid fusion mass of spinal segments in skeletally mature patients.

The ROC™ Lumbar System is intended for posterior, non-cervical pedicle fixation in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities: severe spondylolisthesis (grades 3 and 4), degenerative spondylolisthesis with objective evidence of neurologic impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor and failed previous fusion (pseudarthrosis). The ROC Lumbar Plating System is indicated for placement in L3 – S1.

Substantial Equivalence:

The ROC™ Lumbar System is substantially equivalent to the following predicate devices:

Trade/Proprietary Name	Manufacturer	Clearance
Moss Miami Spinal Fixation	Depuy Moss Miami	K030383
Synthes	USS	K022949

Performance Data:

Mechanical and dynamic testing of the rods, rod connectors as part of a spinal construct using the ROC™ Lumbar System was performed. The test results demonstrate that the mechanical performance of the ROC™ Lumbar System is substantially equivalent to those of the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Alphatec Spine, Inc.
% Paula Morgan
Director of Regulatory Affairs
2051 Palomar Airport Rd, Suite 100
Carlsbad, California 92011

MAY 18 2007

Re: K063668
Trade Name: ROC™ Lumbar System
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: Class II
Product Code: MNH, MNI
Dated: June 9, 2007
Received: June 15, 2007

Dear Ms. Morgan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA) application. You may, therefore, market the device, subject to the general controls provisions of the Act and the limitations described below. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address: http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K063668

Device Name: ROC™ Lumbar System

Indications for Use:

It is intended that this device, in any system configuration, be removed after the development of solid fusion mass of spinal segments in skeletally mature patients.

The ROC™ Lumbar System is intended for posterior, non-cervical pedicle fixation in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities: severe spondylolisthesis (grades 3 and 4), degenerative spondylolisthesis with objective evidence of neurologic impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor and failed previous fusion (pseudarthrosis). The ROC Lumbar Plating System is indicated for placement in L3 – S1.

Prescription Use ___X___ OR Over-The Counter Use _____
(Per 21 CFR 801.109)

(PLEASE DO NOT WRITE BELOW THIS LINE- CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K063668